AUG 2 2 2003

510 k Summary
K022587

H. Safety & Effectiveness: MedTrade *Product's* Antiseptic Barrier Hydrogel Dressings
Classification Name: NAE 878.4022 Bandage Liquid
Contact: Jonathan Ranfield, Director of Quality Assurance & Regulatory Affairs
MedTrade Products Ltd, Electra House, Crewe Business Park, Crewe,
CW1 6GL. UK. Tel: +44 (0) 1270 500019. Fax: +44 (0) 1270 500045
Prepared: August 10, 2002
Description: MedTrade *Product's* Antiseptic Barrier Hydrogel Dressings consist of an Antiseptic Hydrogel, which is over 70% pure water. Effective antiseptic barrier protection of the dressing against microbes and microbial contamination is provided by the antiseptic barrier hydrogel and adhesive film cover of the dressing. The dressing is made from a special Antiseptic Barrier hydrogel formulation which not only has a high water activity (a measure of cooling) but is also capable of absorbing substantial quantities of fluid. This makes it especially suitable for use on burns with minimal risk of maceration. The Antiseptic Barrier hydrogel dressings are highly conformable, soft, absorbent, sterile, primary wound dressings of a gelatinous mass which provides a moist healing environment.

MedTrade *Product's* Antiseptic Barrier Hydrogel Dressings are indicated for OTC use on minor cuts & grazes, minor scalds & burns and insect bites. If at any time you are unsure of the above conditions or type of wound consult a health care professional.

Dressings are supplied sterile in single use pouches. Product is gamma irradiated in accordance with the Sterilisation of Health Care Products – Requirements for Validation and Routine Control – Radiation Sterilisation, 3rd Edition (ANS/AAMI/ISO11137 – 1995) and Microbiological Methods for Gamma Sterilisation (AAMI TIR8-1991) for qualification for Method 1 for dosimetric release with a sterility assurance level of 10^{-6}.
Biocompatability testing including: Dermal Irritation, Dermal Sensitization, Cytotoxicity, Acute Systemic Toxicity and Hemocompatibility/Hemolysis have been successfully completed per ISO/Tripartite guidelines.

MedTrade *Product's* Antiseptic Barrier Hydrogel Dressings are substantially equivalent in design, composition and function to MedTrade Product's Hydrogel Island Dressings K002504, with the addition of an antiseptic, to provide an antiseptic barrier hydrogel. A table of comparative features may be found below.

COMPARATIVE FEATURES

Characteristics	**MedTrade *Product's* Hydrogel Island Dressing Exempted 510(k) K002504**	**MedTrade *Product's* Antiseptic Barrier Hydrogel Island Dressing**
Hydrogel - Composition	High water content medical grade hydrophilic polymer	High water content medical grade hydrophilic polymer
Backing	Self Adhesive Film	Self Adhesive Film
Adhesive	Medical grade pressure sensitive adhesive	Medical grade pressure sensitive adhesive
Adhesive Coverage	100% on backing	100% on backing
Indications For Use	Minor cuts & grazes Minor scalds & burns Insect Bites	Minor cuts & grazes Minor scalds & burns Insect Bites
Packaging	Printed Pouch	Printed Pouch
Supplied	Sterile	Sterile

Additionally, MedTrade Products Antiseptic Barrier Hydrogel has been shown to have "Antiseptic Barrier activity".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 22 2003

Mr. Jonathan Ranfield
Director, Quality Assurance & Regulatory Affairs
MedTrade Products Ltd.
Electra House
Crewe Business Park
Crewe, Cheshire
United Kingdom CW1 6GL

Re: K022587
Trade/Device Name: MedTrade Product's Antiseptic Barrier Hydrogel Dressings
Regulatory Class: Unclassified
Product Code: MGQ
Dated: June 18, 2003
Received: June 20, 2003

Dear Mr. Ranfield:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known) K022587

Device Name: MedTrade *Product's* Antiseptic Barrier Hydrogel Dressings

These dressings are intended for **OTC** use on wounds such as:

- Minor cuts and grazes
- Minor scalds and burns
- Insect bites

MedTrade *Products* Antiseptic Barrier Hydrogel Dressings are contraindicated for:

- Third degree burns

The components do not contain animal ingredients.

(PLEASE DO NOT WRITE BELOW THIS LINE, CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ Or Over The Counter Use_____X_____
(Per 21 CFR 801.190) (Optional Format 1-2-96)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022587